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AMENDED CLAIMS

[received by the International Bureau on 04 February 2005 (04.02.05);
original claims 1-20 replaced by new claims 1-18 (3 pages)]

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1. Pharmaceutical compositions comprising at least one pharmaceutically active ingredient and biodegradable aliphatic polyesters derived from fatty diacids and fatty diols both with even number of carbon atoms; particularly polyethylene sebaccate which is thermally stable, non-toxic, and metabolized by normal lipid metabolism in the form of different drug delivery systems such as drug loaded microparticles, nanoparticles, molded implants, coated granules, injectable sustained release particles, stents, films, matrix tablet, coated tablets, dry syrup, mouth dissolving tablets, microparticles dispersed in gels, taste masked formulation, inserts (ophthalmic), fibers, ligatures and sutures.
2. The compositions as claimed in claim 1, wherein the molecular weight of said polyethylene sebaccate is in the range of 3,000 to 30,000.
3. The compositions as claimed in claim 1, wherein said pharmaceutically active ingredient is selected from anti-hypertensives, cardiovascular agents, analgesics, steroids, physiologically active peptides and / or proteins, anti-cancer agents, antibiotics, fibrinolytics, anti-inflammatory agents, expectorants, muscle relaxants, epilepsy remedies, anti-ulcerative agents, anti-hyperchondriac agents, anti-allergic agents, diuretics diabetes curatives, hyperlipidemic remedies, anticoagulants, hemolytic agents, anti tubercular agents, hormones, anesthetic antagonists, osteoclastic suppressants, osteogenic promotives, angiogenesis suppressors, mydriatics, myotics, glaucoma therapy and or mixtures thereof.
4. The compositions as claimed in claim 1, wherein the drug to polymer ratio in said compositions is from 95:5 to 1:99.
5. The compositions as claimed in claims 1 to 4 wherein said drug delivery system is drug-loaded micro / nano particles.
6. The compositions as claimed in claims 1 to 4, wherein said drug delivery systems are molded implants containing drug.
7. The compositions as claimed in claims 1 to 4, wherein said drug delivery systems are coated granules, prepared by coating the granules with 1-5% solution of said biodegradable aliphatic polyester in a suitable solvent.

8. The compositions as claimed in claims 1 to 4, wherein said drug delivery systems are injectable sustained release microparticles suitable for sub-cutaneous, intra-muscular or periodontal administration for sustained action for the required period.
9. The drug delivery system of novel biodegradable aliphatic polyesters derived from the fatty diacids and fatty diols with even number of carbon atoms in the form of stents as claimed in claims 1 to 4 wherein said stent form is prepared by molding said biodegradable aliphatic polyester into stents after being ablated with laser.
10. The compositions in the form of microparticles dispersed in gel as claimed in claims 1 to 4, wherein said drug delivery system in gel form is prepared by incorporating the micro particles in a gel suitable for the treatment of periodontitis.
11. The compositions in the form of films as claimed in claims 1 to 4, wherein said drug delivery system is self supporting drug loaded films.
12. The compositions in the form of microcapsule as claimed in claims 1 to 4, wherein said microcapsule is sustained release microcapsule.
13. The compositions as claimed in claim 12, wherein said microcapsule can be produced in an oil/water suspension system, in which the drug is embedded within the polymer microparticles forming the oil phase, and stabilizing agents for the microparticles forming the aqueous phase.
14. The composition as claimed in claim 13, wherein the stabilizing agents are selected from polyvinyl alcohol, polyvinyl pyrrolidone, alginate, gelatin, methyl cellulose, polyoxyethylene derivatives of sorbitan fatty esters and polyoxyethylene fatty ethers.
15. The compositions as claimed in claims 12 to 14, wherein particle size of microparticles is in the range of 10 nm to 1000 microns depending on the type and concentration of stabilizer and drug to polymer ratio used in the formulation.
16. The compositions as claimed in claims 1 to 15, wherein said drug delivery systems are with or without the addition of lipase to modify the drug release.

17. The compositions as claimed in claims 1 to 16, wherein said pharmaceutical compositions could be administered by either oral, ophthalmic, parenteral, mucosal or transdermal route.
18. Pharmaceutical compositions comprising at least one pharmaceutically active ingredient and biodegradable aliphatic polyesters derived from fatty diacids and fatty diols both with even number of carbon atoms; particularly polyethylene sebaccate which is thermally stable, non-toxic, and metabolized by normal lipid metabolism in the form of different drug delivery systems as substantially described herein with reference to foregoing examples 1 to 18.

STATEMENT UNDER ARTICLE 19 (1)

We note that the examiners opinion is that claims 1 to 20 do not meet the requirement of Article 33 (2) and (3) and contravenes Article 6 PCT. We hereby amend by replacing the claim 1 as enclosed to expedite prosecution. Our invention is now restricted to pharmaceutical compositions comprising biodegradable polymer particularly polyethylene sebacate.

D10 discloses prior art WO94/10982 which describes polyalkylene oxalate, while D19 claims polyethylene oxalate, in non pharmaceutical applications. D2 describes polyethylene sebacate its synthesis and applications for the preparation of bottles. D9 D11 and D12 disclose polymer or copolymer derived from unsaturated cyclic diols butane diol and 1,12-dodecane diol respectively. D13 describes preparation of aliphatic polyesters of adipic acid/sebacic acid/dodecanoic acid with succinic acid useful in films. D15 describes a polyester wax for use in coatings.

D1, D5, and D8, discuss the use of polyalkylene oxalate in prosthesis, parenteral administration, and periodontal disease including a bioactive agent respectively. D8 also describes use of polyalkylene succinate and copolymers and terpolymers of polyalkylene succinate/oxalate. D3 and D4 disclose surgical articles comprising copolycondensate of succinic/oxalic acids.

D6 describes pharmaceutical compositions comprising drug and polyalkylene succinates. D7 and D18 describe nanocapsules and microcapsules prepared from polyethylene adipate/butyrate and polyethylene and polybutylene adipate respectively with active principle for cosmetic/dermatological use. D16 describes microcapsules using polyethylene adipate alone or blended with polyhydroxy butyrate–hydroxy valerate. D14 describes medicinal aerosol formulation comprising drug and diol-diacid condensate. Acids excluding sebacic acid are disclosed on page 4 line 7 to 21 of this patent. D17 describes an implantable medical device with a polymer different from polyethylene sebacate.

The prior art does not cover pharmaceutical compositions comprising polyethylene sebacate. Polyethylene sebacate is hydrophobic, very stable, non-toxic and degrades enzymatically. Most of the prior art talk about polyalkylene oxalate and pharmaceutical

compositions comprising the same. Biodegradation of polyalkylene oxalate releases oxalic acid which is harmful to humans. Thus, Polyethylene sebacate is safer than polyakylene oxalate.

We further state as follows:

- Use of polyethylene sebacate is not tried or reported by anyone skilled in the art.
- The compositions of the present invention comprise stable and non-toxic polyethylene sebacate, making them novel over the prior art.
- The inventive step is now clearly distinguished over quoted prior art.

Therefore it is respectfully submitted that a person "skilled in the art" would never be led to prepare pharmaceutical compositions comprising drug and polyethylene sebacate as claimed in the present application as amended, without the exercise of inventive skill. This makes the present application novel and inventive over the disclosure in the cited document.

It is submitted that the above application is now in order to proceed for the publication, however, should the examiner, unexpectedly, have any further objections, the primary examiner is respectfully requested to communicate the same.